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Virginia Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Board Members Reappointed

Virginia Board of Pharmacy members are appointed by the governor for a four-year term, not to exceed two consecutive full terms. This year there were two Board members eligible for reappointment. The first was the position held by Gill B. Abernathy. Ms Abernathy completed her first full, four-year term in June 2008 and was recently reappointed to a second full, four-year term, which will end on June 30, 2012. The second eligible position for reappointment was the position held by Brandon K. Yi. Mr Yi replaced Ms Toni Aust in 2006 when Ms Aust resigned from her Board member position to accept a position as a pharmacy inspector for the Department of Health Professions. The full term held by Ms Aust was not due to expire until June 2008; therefore, Mr Yi was appointed at that time to fill the vacancy for the duration of the unexpired term. Mr Yi has now been reappointed to his first full, four-year term, which will end on June 30, 2012.

The Board would like to congratulate Ms Abernathy and Mr Yi for their recent reappointments. For a complete listing of Board members, please click on *www.dhp.virginia.gov/pharmacy/pharmacy_board.htm*.

Faxed Schedule II Prescriptions for Hospice Patients

The Board has received a number of questions recently from pharmacies receiving faxed Schedule II prescriptions for hospice patients. Pharmacists may be mixing up their knowledge of the laws and regulations related to oral emergency Schedule II prescriptions with the laws and regulations that allow for faxed prescriptions for hospice patients since many of these also constitute an emergency. Please note that a pharmacist may dispense a Schedule II drug for a hospice patient from a prescription faxed to the pharmacy if it complies with Board regulation 18VAC110-20-280, *www.dhp.virginia.gov/Pharmacy/leg/Pharmacy%208-6-08.doc#_Toc153072935*. The prescriber shall note on the prescription if the patient is a hospice patient; and the prescription shall meet all requirements for a written prescription, to include containing the prescriber's signature. A hospice nurse may not sign the prescription in lieu of the prescriber.

The prescriber or prescriber's agent may fax the prescription directly from the prescriber's practice location to the pharmacy. A prescriber's practice location is wherever the prescriber is evaluating a patient's condition. If the prescriber is contacted at home regarding a patient's condition and determines that issuing a prescription is appropriate for the patient's treatment, then his or her home is serving as the practice location, and it would be acceptable for the prescriber to fax a prescription from his or her home to the pharmacy.

One source of confusion appears to result from the language in the regulation, which states that the allowance is "for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state." This statement is not intended to imply that the patient must reside in a facility. The regulation is intended to allow for the faxing of a Schedule II prescription for any patient participating in a certified or licensed hospice program, regardless of whether the patient resides in a private residence or a licensed facility.

Confusion also exists regarding the allowable quantity that may be prescribed for a hospice patient. Some believe that a prescription for a hospice patient may not exceed a 30-day supply. There is no law within the purview of the Board of Pharmacy or Drug Enforcement Administration that restricts the allowable prescribed quantity. The prescriber may prescribe whatever quantity he or she feels is appropriate for treating the patient. Some pharmacists are also requiring the prescriber to mail a hard copy prescription to the pharmacy to cover the faxed Schedule II prescription; however, this is not necessary. The regulation states that the faxed Schedule II prescription for a hospice patient may serve as the hard copy; therefore, no additional follow-up is required by the prescriber.

Renewing Pharmacist Licenses and Pharmacy Technician Registrations

In mid-November, pharmacists and pharmacy technicians will be receiving notification letters sent from the Board alerting them to the fact that it is time to renew their licenses or registrations. Licenses may not be renewed until the letters are sent out. The renewal fees and continuing education (CE) requirements are as follows:

- Pharmacist active license – $90 and 15 hours approved CE;
- Pharmacist inactive license – $45 (CE requirements deferred until reactivation is requested); and,
- Pharmacy technician registration – $25 and 5 hours approved CE.

As part of the renewal process, each pharmacist or pharmacy technician must verify that he or she has successfully obtained, or will have obtained prior to December 31, the required CE hours

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Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

Testing Medication Names Prior to Marketing

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!®*** ***Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (*www.fda.gov/cder/drug/MedErrors/meeting_names.pdf*) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of

errors and potential errors caused by look-and sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc®, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to *www.med-errs.com* and click on "Become a Reviewer."

Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain statewide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

FDA Encourages Pharmacists to Use Patient Safety News

FDA Patient Safety News is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at *www.fda.gov/psn* or by sending an e-mail to PSNews@cdrh.fda.gov.

Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair® HFA Inhalation Aerosol, Proventil® HFA Inhalation Aerosol, and Ventolin® HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex® HFA Inhalation Aerosol. More information is available on the FDA Web site at *www.fda.gov/cder/mdi/albuterol.htm*.

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during the 2008 calendar year. Approved CE courses are those courses that are:

1. Accreditation Council for Pharmacy Education (ACPE)-approved;
2. approved category I continuing medical education (CME) programs of which the primary focus is pharmacy, pharmacology or drug therapy; or
3. other programs if approved by the Board in advance of the program being given and pursuant to an application from the CE provider.

The Board will not approve a program pursuant to a request from an individual taking the program.

Once the renewal letter is received, the license or registration may be renewed online using a Visa® or MasterCard® by going to *www.license.dhp.virginia.gov*, entering the user ID and password, and clicking on "renew license."

Persons who do not remember their user ID and password from the previous renewal year may click on "new user," enter their license number and the temporary personal identification number (PIN) provided in the renewal letter. Using the license number and PIN number provided in the letter will override any previously designated user ID and password.

As always, pharmacists and pharmacy technicians are encouraged to renew online, but there will be instructions in the renewal letter for requesting a paper renewal. Pharmacists and pharmacy technicians must provide an attestation that they have obtained the required CE. Persons should not go forward with the renewal process without having the required CE. If a person selects "no," that CE requirements have not been met, the system will still allow the person to renew, but an alert will be sent to the Board. Renewing without obtaining required CE may result in disciplinary action. Additionally, a false attestation is usually cause for an increased sanction. Persons who cannot complete CE requirements prior to renewal should request an extension for obtaining the CE. The request must be made in writing and needs to be made before attempting to renew. A one-time extension may be granted upon written request. If a pharmacist or pharmacy technician has already received an extension in the past, a second extension will be granted for good cause only. An approved extension does not exempt the individual from obtaining the necessary number of CE credits needed in 2008. An extension simply allows the individual to obtain the CE beyond the December 31, 2008 deadline, and means that the 2008 CE must be made up in 2009 in addition to the 2009 requirement. Anyone who requests an extension will be audited the following year and will be required to submit original CE documents to verify compliance for the total number of hours required for the prior two years, ie, 30 hours for pharmacists and 10 hours for pharmacy technicians. More information related to CE may be found in guidance document 110-4 located at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

While renewing online, if there have been changes, pharmacists and pharmacy technicians are asked to update their e-mail address and their address of record for the Board, and provide or update the required Emergency Contact Information. A current e-mail address is needed for the Board to send the quarterly e-newsletter notifications.

Expiration Date for Pharmacy Permits Pushed Back

The draft emergency amendments to the regulations that would allow pharmacy permits and nonresident pharmacy registrations to expire on April 30 annually, and all other facility permits, licenses, or registrations to expire on February 28 annually have become final. Therefore, pharmacy permits will not expire on December 31, 2008, and thus, the permits do not need to be renewed prior to December 31. All pharmacy permits will now expire on April 30 annually. A new permit with the April 30, 2009 expiration date will be sent to all pharmacies in November. Please post this amended permit in a conspicuous place as required by §54.1-3430, *www.dhp.virginia.gov/Pharmacy/leg/Pharmacy%20Law%207-2008.doc#_Toc171834228*, and remove the pharmacy permit containing the expiration date of December 31, 2008.

A renewal notification letter will be sent to all pharmacies in approximately mid-March 2009. It will provide appropriate instructions for completing the renewal process. Pharmacies wishing to request batch renewals should make such request to the Board no later than March 2, 2009.

Pharmacy Interns Must be Registered with the Board

In order to gain practical experience hours needed for licensure as a pharmacist in a pharmacy located in Virginia, an individual must first obtain a pharmacy intern registration from the Board. An intern registration may be issued to a student who is enrolled in an approved school of pharmacy in Virginia or it may be issued to a student who is enrolled in an approved school of pharmacy located in another state, but wishes to obtain hours of practical experience in a pharmacy located in Virginia. A pharmacy intern registration may also be issued to a qualified graduate of a foreign college of pharmacy needing to obtain hours of practical experience or a pharmacist licensed in another state who has not practiced the number of hours equivalent to the hours of practical experience needed for licensure in Virginia. Please note that registration as a pharmacy intern in another state does not qualify the individual to obtain hours of practical experience in Virginia. There have been situations where students enrolled in out-of-state pharmacy schools have worked for an entire summer in a Virginia pharmacy, but never obtained a pharmacy intern registration from the Virginia Board of Pharmacy. Without being registered, these hours will not qualify for meeting the required number hours of practical experience. Pharmacists can help prevent this situation from occurring by ensuring that all pharmacy interns gaining hours of practical experience are appropriately registered with the Virginia Board of Pharmacy.

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